

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

THOMAS FOGLIA, in the name	:	
of the United States	:	
Government pursuant to the	:	
False Claims Act, 31 U.S.C.	:	Civ. A. No. 09-1552 (NLH) (AMD)
Section 3730; the State of	:	
New Jersey False Claims Act,	:	
Title 2A of the New Jersey	:	
Statutes and amending	:	
3 P.L. 1968, c.413; the State	:	OPINION
of Texas pursuant to	:	
TEX.HUM.RES.CODE Sec.	:	
36.001-36.117 and individually:	:	
pursuant to the New Jersey	:	
Conscientious Employee	:	
Protection Act, N.J.S.A.	:	
34:19-1 et seq.,	:	
Relator/Plaintiff,	:	
	:	
v.	:	
	:	
Renal Ventures Management,	:	
LLC,	:	
Defendant.	:	

APPEARANCES:

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HILLMAN, District Judge:

This matter involves a qui tam claim under the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., arising out of allegedly fraudulent claims for Medicare funds.¹ Before the Court is a motion for partial dismissal of the second amended complaint pursuant to Fed. R. Civ. P. 12(b)(6) filed by

¹ The federal False Claims Act prohibits the submission of false or fraudulent claims for payment to the United States and authorizes qui tam actions, by which private individuals may bring a lawsuit on behalf of the government in exchange for the right to retain a portion of any resulting damages award. Schindler Elevator Corp. v. U.S. ex rel. Kirk, ___ U.S. ___, 131 S. Ct. 1885, 1889, 179 L. Ed. 2d 825 (2011); U.S. ex rel. Wilkins v. United Health Group, Inc., No. Civ. A. 10-2747, 2011 WL 2573380, at *1 n.1 (3d Cir. June 30, 2011).

defendant, Renal Ventures Management, LLC. The Court has considered the parties' submissions, and for the reasons that follow, defendant's motion will be granted.

I. BACKGROUND

A. Factual Background

The facts in this case were summarized by the Court in its previous opinion, Foglia v. Renal Ventures Management, LLC, --- F.Supp.2d ---, 2011 WL 5882020 (D.N.J. Nov. 23, 2011), and will not be repeated here.

B. Procedural Background

As stated in its previous Opinion, the Court granted in part and denied in part defendant's motion on the pleadings, and granted plaintiff leave to file an amended complaint. Id. at 13. On December 13, 2011, relator² filed a timely second amended complaint. Relator brought claims pursuant to the Federal False Claims Act (FCA),³ the New Jersey False Claims Act, and the New

2 Relator refers to relator/plaintiff Thomas Foglia.

3 As stated in the Court's prior Opinion:

On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), which amended the FCA and now imposes liability on:

[A]ny person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

Jersey Conscientious Employee Protection Act. Defendant moves to dismiss plaintiff's federal claims under the FCA.

II. DISCUSSION

A. Subject Matter Jurisdiction

This Court has jurisdiction over relator's federal claims under 28 U.S.C. § 1331, and may exercise supplemental jurisdiction over relator's related state law claim under 28 U.S.C. § 1367.

B. Motion to Dismiss

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a court must accept all allegations in the complaint as true and view them in the light most favorable to the plaintiff. See Evancho v. Fisher, 423 F.3d 347, 350 (3d Cir. 2005). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to

31 U.S.C. § 3729(a)(1). Pursuant to the amendment, Section 3729(a)(2) of the pre-FERA statute was renumbered as Section 3729(a)(1)(B) and expanded liability to anyone who submitted statements which are material to receipt of government funds, even if such statements were not made to induce the government directly to pay the funds.

Id. at *6. As this Court explained, analysis under both FCA and FERA is the same in this case since FERA addressed an "intent requirement" which is not at issue here since plaintiff alleged that defendant's statements were made directly to the government and not a third party. Id. at *7.

relief.” Fed. R. Civ. P. 8(a)(2).

A district court, in weighing a motion to dismiss, asks “‘not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims[.]’” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 563 n.8 (2007) (quoting Scheuer v. Rhoades, 416 U.S. 232, 236 (1974)); see also Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 1953 (2009) (“Our decision in Twombly expounded the pleading standard for ‘all civil actions[.]’”) (citation omitted). The Third Circuit has instructed district courts to conduct a two-part analysis in deciding a motion to dismiss. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009).

First, a district court “must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions.” Fowler, 578 F.3d at 210-11 (citing Iqbal, 129 S. Ct. at 1949). Second, a district court must “determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a ‘plausible claim for relief.’” Id. at 211 (quoting Iqbal, 129 S. Ct. at 1950). “[A] complaint must do more than allege the plaintiff’s entitlement to relief.” Id. “‘[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘show[n]’ – ‘that the pleader is entitled to relief.’” Id. (quoting Iqbal, 129 S. Ct. at 1949);

see also Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) ("The Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element.") (quoting Twombly, 550 U.S. at 556).

A court need not credit "'bald assertions'" or "'legal conclusions'" in a complaint when deciding a motion to dismiss. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429-30 (3d Cir. 1997). The defendant has the burden of demonstrating that no claim has been presented. Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005) (citing Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)).

Since the second amended complaint alleges violations of the FCA and because FCA claims implicate fraud statutes, relator's allegations with respect to these claims must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998) (noting that Rule 9(b) "requires plaintiffs to plead fraud with particularity, specifying the time, place and substance of the defendant's

alleged conduct[,]” and thus “provides sufficient deterrence against overly broad allegations” under the False Claims Act).

In his second amended complaint, relator alleges that defendant violated the FCA by: (1) falsely certifying that it was in compliance with all State regulations when it had violated certain sections of the New Jersey Administrative Code (NJAC); and (2) by falsely submitting claims for use of the drug Zemplar for amounts in excess of what was actually administered at defendant’s facility. Defendant raises two challenges in its motion to dismiss relator’s allegations. First, defendant argues that relator has failed to plead the allegations with particularity as required under Rule 9(b). Second, defendant argues that under either an express or implied false certification theory, relator cannot show that defendant violated a regulation which required compliance as a condition of payment from the Government.

Regarding defendant’s Rule 9(b) challenge, as set forth below, relator’s first claim - that defendant falsely certified it was in compliance with all State regulations when it had violated certain sections of the NJAC - is plead with enough particularity to satisfy the standard under 9(b) for FCA claims. However, relator’s second claim - that defendant falsely submitted claims for use of the drug Zemplar for amounts in excess of what was actually administered at its facility - is not

plead with enough particularity to satisfy Rule 9(b) requirements.

C. Rule 9(b)

The Third Circuit has held that "plaintiffs must plead FCA claims with particularity in accordance with Rule 9(b)."

U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 301 n.9 (3d Cir. 2011) (citing U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., 149 F.3d 227, 234 (3d Cir. 1998)).

Federal Rule of Civil Procedure 9(b) states, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." See Craftmatic Securities Litigation v. Kraftsow, 890 F.2d 628, 645 (3d Cir. 1989) ("Fed.R.Civ.P. 9(b) requires plaintiffs to plead the circumstances of the alleged fraud with particularity to ensure that defendants are placed on notice of the 'precise misconduct with which they are charged, and to safeguard defendants against spurious charges' of fraud.").

Defendant argues that for an FCA claim, the "actual submission of a false claim must be shown." Third Circuit made clear, however, that *at the pleading stage*, Rule 9(b)'s particularity requirement does not require a plaintiff to "identify a specific claim for payment at the pleading stage of the case to state a claim for relief." Wilkins, 659 F.3d at 308.

Rather, the Third Circuit suggested that a plaintiff "identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly."⁴ Id. (remanding the issue to the District Court). Courts in this District have found that a plaintiff may satisfy that requirement in one of two ways: (1) "by pleading the date, place or time of the fraud;" or (2) using an "alternative means of injecting precision and some measure of substantiation into their allegations of fraud." U.S. ex rel. Wilkins v. United Health Group, Inc., No. 08-3425, 2011 WL 6719139, at *2 (D.N.J. Dec. 20, 2011) (on remand from the Third Circuit) (citing Lum v. Bank of Am., 361 F.3d 217, 223-24 (3d Cir. 2004)).

Relator alleges that he observed defendant's failure to provide the required nurse to patient ratio in accordance with

4 The Third Circuit specifically stated, "In any event, as appellants correctly point out, the question of whether a plaintiff, at the pleading stage, must identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly is a requirement under the more particular pleading standards of Rule 9(b)." Id. at 308 (citing Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010)). In Ebeid, the Ninth Circuit found that "use of representative examples is simply one means of meeting the pleading obligation." Id. The Ninth Circuit joined the Fifth Circuit in concluding, "in accord with general pleading requirements under Rule 9(b), ... it is sufficient to allege 'particular' details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id. at 998-99 (citing United States ex rel. Grubbs v. Ravikumar Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)).

8:43A-24.7(c) and (d) of the New Jersey Administrative Code (NJAC). He lists by date 19⁵ instances in which he alleges there was insufficient nurse or staff to patient ratio, or other violations. Relator argues that compliance with the NJAC is both a condition of participation and a condition of payment pursuant to 42 CFR § 494.20.⁶ Relator states that defendant falsely certified that it was compliant with State regulations regarding quality of care. Thus, the scheme that plaintiff seems to allege is that defendant failed on 19 occasions to comply with State regulations, but nevertheless certified that it did in order to receive payment from the U.S. Government.

Relator also alleges that defendant submitted claims for payment for the drug Zemplar based on full use of each vial of the drug even though there were unused portions of vials. In support of this assertion, relator relies on log sheets maintained by defendant for October 2008 which indicate "a range

5 Relator also alleges generally that 90-95% of the time, the Renal Center of Sewell operates with 22-23 patients, which is more than the licensed maximum of 18.

6 42 CFR § 494.20, states:

Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

of 29 to 35 vials used per day, when based on patients [sic] prescription [sic] for October 29 and October 31, [the total number of patients per day would indicate] that 50 [vials] would be used if the defendant were following the prescribed clinical guidelines of not using 'unused' portions from a vial that was already used." Relator states that defendant permitted multiple use of single use vials of Zemplar which is contrary to the FDA approved label. Relator argues that defendant falsely submitted claims for reimbursement to the U.S. Government for payment based on full use of each vial of Zemplar for a patient even though it used unused portions of vials on subsequent patients. Therefore, plaintiff seems to allege that defendant was improperly reusing Zemplar vials and falsely certifying that it was in compliance with clinical guidelines in order to receive payment from the U.S. Government.

Although not factually robust, plaintiff has plead enough facts to survive a Rule 9(b) challenge at the pleading stage with regard to his first claim that defendant falsely certified it was compliant with State regulations in order to receive payment from the U.S. Government. Although he does not submit any evidence of an actual false claim, the Third Circuit does not require such particularity at this stage. See Wilkins, 659 F.3d at 308; see also U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) (holding that "to plead with

particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

Relator has not, however, plead enough particularity regarding the administration of Zemplar that would give rise to an FCA claim. All that relator has plead is a presumed discrepancy between the actual vials used and what relator believes should have been used. Based on what relator believes should have been used, he then assumes that defendant improperly billed the U.S. Government. Relator's beliefs and assumptions of fraud do not provide the particularity required under Rule 9(b). Furthermore, as noted by the Court in its previous Opinion, relator "fails to set forth with any specificity even a single occasion on which a vial containing leftover Zemplar was administered to a patient." Foglia 2011 WL 5882020, at *11. The Court also previously noted that relator failed "to cite a particular rule or regulation that prohibits the reuse of Zemplar." Id. Rather, in his second amended complaint (§ 32), relator acknowledges that the CDC permits multiple uses of single use vials as long as certain precautions are followed.

Thus, relator has not provided a representative sample or otherwise plead particular details of a scheme with reliable indicia that could lead to a strong inference that false claims were actually submitted. See Ebeid, 616 F.3d at 999 (finding that relator failed to "state with particularity the circumstances constituting fraud or mistake," as required by Rule 9(b)) based on his allegation that the U.S. would not have paid the claim had it known of the noncompliance with state and federal laws); Wilkins, 2011 WL 6719139, at *2 (finding relator did not meet 9(b) requirement because the allegation that AmeriChoice paid \$27,000.00 to induce Reliance to switch eligible clients to AmeriChoice coverage did not include the "date, place or time of the fraud."). Accordingly, this claim does not meet the requirements under Rule 9(b) and shall be dismissed.⁷

⁷ Even if this claim met Rule 9(b), relator has provided no authority under an express or implied false certification theory that the claims submitted by defendant violated a rule or statute establishing compliance as a condition of payment. Relator has stated that HHS issued a "program memorandum" dated September 12, 2002, in which it states that it expects End Stage Renal Disease (ESRD) facilities to follow the revised CDC recommendations for injectable medications administered at ESRD facilities, and that failure to comply poses a significant health and safety risk to patients. The revised "recommendations" are not "conditions of payment" and there is no reference at all regarding Medicare payments. Relator also relies on Section 1395y(a)(1)(A) of the Medicare Act which states, "no payment may be made ... for any expenses incurred for items or services ... which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." As stated above, relator has not plead any facts that could show the actual amounts of Zemplar administered to

Although relator survives a Rule 9(b) challenge on his first claim alleging defendant falsely certified it was compliant with State laws, he has not, under either an express or implied false certification theory, plead facts that could show that compliance with a regulation allegedly violated by defendant was a condition of payment from the U.S. Government.

D. False Certification Theory Under Federal False Claims Act.

A plaintiff may proceed under two theories of legally false claims under the FCA: express false certification and implied false certification. Wilkins, 659 F.3d at 305. "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." Id. (citing Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by U.S. ex rel. Eisenstein v. City of New York, 556 U.S. 928, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009)). Under the "implied false certification" theory, a claimant "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." Id. Under either an express or implied false certification theory, a

patients were not reasonable and necessary.

plaintiff "must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government." Id. at 309.

Relator argues that defendant submitted false claims to the Government in violation of NJAC 8:43A-24.7(c) which requires at least one registered nurse be on duty for the first nine patients receiving dialysis services, and an additional registered nurse be on duty for each additional nine patients, and in violation of NJAC 8:43A-24.7(d) requiring at least one registered nurse, licensed practical nurse, or trained patient care technician to be on duty for every three patients receiving dialysis services. Relator alleges that this noncompliance with the NJAC violates 42 CFR § 494.20 which requires that the facility comply with all applicable Federal, State and local laws.⁸ Relator argues that failure to comply with 42 CFR § 494.20, will subject the facility to termination of participation in the Medicare program and denial of payment pursuant to the following regulations: 42 CFR § 488.604, 42 CFR § 488.606, and 42 CFR § 488.608.⁹

Title 42, part 488.604 is titled "Termination of

⁸ See footnote 6, supra.

⁹ The Court had found in its previous Opinion that relator failed to reference any rule, regulation or other source to support his allegation that compliance with state and local regulations were conditions of payment. See Foglia, 2011 WL 5882020, at *10.

Medicare coverage” and states:

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD¹⁰ services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.180(I) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

Title 42, part 488.606 is titled “Alternative Sanctions” and states:

a) *Basis for application of alternative sanctions.* CMS¹¹ may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

10 End Stage Renal Disease.

11 Centers for Medicare and Medicare Services, part of the U.S. Department of Health and Human Services.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

Title 42, part 488.608 is titled "Notice of alternative sanction and appeal rights: Termination of coverage" and states:

(a) Notice of alternative sanction. CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) Appeal rights. Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

At the outset, subparts 604 and 608 make no reference to payments at all. Therefore, they do not impose conditions of payment. Although subpart 606 does mention the denial of

payments, the denial of payment is part of an alternative sanction to termination of Medicare coverage. Subpart 606 states that CMS *may*, as an alternative to termination of Medicare coverage, impose denial, reduction or withholding of payments. Therefore, the denial, reduction or withholding of payments is not a requirement, but just a possibility in determining alternative sanctions. There are also two requirements that must be met before CMS can consider whether to impose the alternative sanction: the supplier must fail to participate in the activities and goals of the ESRD network; and the failure must not jeopardize patient health and safety. If both requirements are met, then CMS can consider whether to impose monetary sanctions rather than termination. Even so, the monetary sanctions do not impose complete denial of coverage, but permit a provider to receive reduced or delayed payments. See U.S. (Blundell) v. Dialysis Clinic, Inc., No. 09-710, 2011 WL 167246, at *19 (N.D.N.Y. Jan. 19, 2011) ("Indeed, § 488.606 permits a provider to receive Medicare payments during a period of non-compliance with 42 CFR § 494 et seq.").

Overall, the regulations cited by relator establish conditions of participation, not conditions of payment. See id. ("The language in 42 C.F.R. § 494 clearly establishes a condition of participation, not prerequisites to receiving reimbursement from the government."). Relator has not shown that compliance

with the above regulations was a condition of payment from the U.S. Government. Therefore, relator has failed to make a claim under the FCA and defendant's motion will be granted.

III. CONCLUSION

Defendant's motion to dismiss will be granted and relator's federal FCA claim shall be dismissed.¹² Defendant has not moved to dismiss relator's claims brought pursuant to the New Jersey False Claims Act, or the New Jersey Conscientious Employee Protection Act. However, because relator's federal claims are dismissed, and because this case is still at the pleading stage, the Court declines to exercise supplemental jurisdiction over his state law claims. See 28 U.S.C. § 1367(c)(3) (providing that a district court may decline to exercise supplemental jurisdiction over state law claims when it "has dismissed all claims over which it has original jurisdiction"); Elkadrawy v. Vanguard Group, Inc., 584 F.3d 169, 174 (3d Cir. 2009) (affirming district court's dismissing state law claims after federal claims were dismissed). Accordingly, relator's state law claims are dismissed without prejudice with leave for relator to refile in

¹² Relator's federal claims are dismissed with prejudice. After twice amending his complaint and engaging in initial discovery, relator has not presented any grounds that could show further amendment would not be futile. See Phillips v. Cty. of Allegheny, 515 F.3d 224, 236 (3d Cir. 2008) ("if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile.") (citations omitted).

state court. Id.

An Order consistent with this Opinion will be entered.

/s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.

At Camden, New Jersey

Dated: September 26, 2012